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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/589,102	10/05/2007	Tae-Yoon Kim	BARUN-13046	5838

72960 7590 08/05/2009
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EXAMINER	
NOBLE, MARCIA STEPHENS	

ART UNIT	PAPER NUMBER
1632	

MAIL DATE	DELIVERY MODE
08/05/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/589,102	KIM ET AL.	
	Examiner	Art Unit	
	MARCIA S. NOBLE	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-17,20 and 21* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-17, 20, and 21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *10 August 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *5/18/2009*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of Claims

Claims 1-17, 20, and 21 are pending. Claims 1, 7, 11, 14, 16, and 17 are amended and claims 20 and 21 are newly added by the amendment filed 5/18/2009. Claims 1-17, 20, and 21 are under consideration.

Withdrawn Rejections/Objections

The rejection of claims 18 and 19, under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101, set forth in the Office Action, mailed 2/18/2009 (p. 4), is withdrawn.

The objection to claims 18 and 19 under 37 CFR 1.75 as being duplicates each other, as set forth in the Office Action, mailed 2/18/2009, is withdrawn.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States

only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 16 and 17, as amended, are rejected under 35 U.S.C. 102(e) as being anticipated by Cao et al (US2003/0233675 pub date 12/18/2003; filing date 2/20/2003 now Patent Number 7,314,974).

Cao et al discloses SEQ ID NO:24511 (see claim 1 of Pregrant Pub). Nucleic acids 208-189 are identical to SEQ ID NO:8. The claimed composition does not specify that the composition can only comprise the 20 nucleic acid of the formula. The intended use of the composition is not given patentable weight as there is no indication the use alters the structure of the CpG oligodeoxynucleotide. Therefore, the sequence disclosed by Cao et al encompasses the limitations of the claims.

Response to Arguments

Applicant's arguments filed 5/18/2009 have been fully considered but they are not persuasive. Applicant asserts that Cao et al does not teach an isolated CpG oligonucleotide, as the amended claims require. Thus, Cao et al does not disclose the instantly claimed composition.

Applicant's arguments are not found persuasive because Cao et al discloses SEQ ID NO: 24511 as part of a recombinant DNA construct comprising SEQ ID NO:24511 (claim 1). Cao et al further define recombinant constructs as polynucleotides that are constructed or modified outside of cells (p. 6, [0061], lines 1-6). Thus, contrary to Applicant's assertion, Cao et al discloses an isolated CpG that comprises the sequence of SEQ ID NO:8. If is acknowledged that the sequence of Cao et al

comprises additional sequences. However, the language of the claims recites "comprising" therefore additional sequences can be present in addition to the 20 nucleotides of SEQ ID NO:1 and the polynucleotide sequence of SEQ ID NO:8. Additionally, the claim recites that the CpG is "isolated." However, the term "isolated" does not distinguish from the art of Cao because there is no specific degree of isolation required. Isolation encompasses, for example, extraction of a DNA sequence from a particular source, but does not exclude other additional sequences from being present. Given that the language of the claim is open, Cao is proper and maintained. Thus, Applicant's argument is not found persuasive and the rejection is maintained.

Claims 1-17, 20 and 21, as amended and newly added, are rejected under 35 U.S.C. 102(e) as being anticipated by Rosen et al (US2007/015271 filing date 4/2/2003).

Rosen et al discloses administering a nucleic acid encoded by SEQ ID NO: 976 to a patient for the treatment or prevention of a disease (p. 4, [0026], line 1 to [0029], line 8). Nucleic acids 86-105 of SE ID NO: 976 disclosed by Rosen et al are identical to the nucleic acid sequence of SEQ ID NO: 2. The claims do not require that the nucleic acid of the formula only comprise the 20 nucleic acid sequence. Therefore, the disclosure by Rosen et al encompasses the limitations of the isolated nucleic acid of the claimed sequence. Further, the only active method step of the claims is administering the claimed nucleic acid to a subject and Rosen et al discloses this active method step.

The claims do recite an intended use or a desire result of the method in the preamble of the claims. Newly added claims 20 and 21 specify aspects of the skin disease recited in the preamble. However, because these limitations are not active method steps in the claimed method, these intended uses and results do not have patentable weight. Therefore, clearly Rosen et al teaches all of the required limitations of the claims.

Response to Arguments

Applicant's arguments filed 5/18/2009 have been fully considered but they are not persuasive. Applicant asserts that the amended claims do not disclose an "isolated" nucleic acid of SEQ ID NO:1 and Rosen et al does not teach these limitations. Applicant further asserts that Rosen et al does not teach treatment of a skin disease. Thus Applicant asserts that Rosen et al does not teach of the limitations of the claims.

Applicant arguments are not found persuasive because Rosen et al discloses that the invention encompasses isolated nucleic acids encoding proteins/polypeptides useful for treating and/or ameliorating diseases (p. 1, [0007], lines 1-5). Thus contrary to Applicant's assertion, Rosen et al does teach an "isolated" nucleic acid of SEQ ID NO:1. Further as previously discussed above and in the previous Office Action, it is acknowledged that Rosen does not teach a skin disease. However, treating a skin disease is part the preamble and is not an active step in the method, thus is not given patentable weight. The claimed method only requires administering the claimed nucleotides sequence to a subject with no active treating step. Rosen discloses the same method steps (ie-administering the claimed nucleic acid sequence to a patient), thus if the method steps are the same, inherently the effect should also be the same.

Thus, since Rosen discloses the active method steps of the invention, Rosen discloses the all of the patentable limitations of the claims.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 11-15, 20 and 21, as amended or newly added, are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of treating an inflammatory skin disease comprising administering to a subject in need thereof an effective amount of a CpG oligodeoxynucleotide (ODN) comprising the formula SYYSSAGGTTSNYRAWYTC (SEE ID NO:1), wherein S is G or C; Y is C or T; N is any one selected from the group consisting of A, G, T, and C; R is G or A, W is A or T, and M is A or C, and wherein the CpG ODN comprises at least two unmethylated CpG motifs, does not reasonably provide enablement for a method of treating or preventing any skin disease other than an inflammatory skin disease. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The claims recite a method of treating or preventing a skin disease. The breadth of this recitation encompasses the treatment of any skin disease. The specification teaches a method of topically administering CpG ODN to the skin of NC/Nga mice

comprising atopical dermatitis (p. 33, line 20 to p. 34, line 2). The specification teaches that such CpG administration resulted in disappearance of the atopic dermatitis lessions where as control treatment did not (p. 34, lines 5-16). Therefore, the specification provides specific guidance, at the very most, to teach treatment of inflammatory skin disease or skin disease associated with Th2 immune response. The specification contemplates prevention of a skin disease. However, the specification fails to provide specific guidance to teach methods of preventing a skin disease. The prevention of a skin disease would require knowledge that the disease was to occur, and then, utilizing the instantly claimed methods, prevent the occurrence of the disease. The specification provides no guidance for how to determine if or how an individual would be at risk for any type of skin disease, as encompassed by the claims, and then, how utilizing these methods could prevent the onset of the disease.

Najar and Dutz (J Invest Derm 128:2204-2210, 2008) teach a method of coadministering CpG to skin tumor bearing mice with or without chemotherapy. While CpG alone or in combination with chemotherapy were capable retarding the growth of tumors, treatment was not able to prevent skin cancer or mortality associated with skin cancer (p. 2205, col 2, Figure 1a and b). Therefore, the art teaches that treatment with CpG is not capable of prevent such skin diseases as skin cancer, as is encompassed by the claims.

Therefore the instant claim are not enabled for their full breadth because the specification fails to teach a method of preventing a skin disease using CpG treatment and the art suggests that CpG will not prevent skin disease, such as skin cancer.

Therefore at the time of filing the skilled artisan would need to perform an undue amount of experimentation without a predictable degree of success to implement the invention as claimed.

Response to Arguments

Applicant's arguments filed 5/18/2009 have been fully considered but they are not persuasive. Applicant asserts that the amended claims now recite, "a method of treating a skin disease", and that these amendment enable the instant invention. Applicant's arguments are not found persuasive because the claim previously recited "treating a skin disease". However, as previously discussed above, the specification fails to teach a means of treating any and all skin disease. Further Najar and Dutz teaches that CpG oligonucleotide treatments were not effective in skin cancer treatment, which is a skin disease. These the art suggests that CpG do not predictably treat skin diseases as claimed. Thus, Applicant's arguments are not found persuasive and the rejection of record is maintained.

No claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not

mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MARCIA S. NOBLE whose telephone number is (571)272-5545. The examiner can normally be reached on M-F 9 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras can be reached on (571) 272-4517. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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